

CHAPTER 83
LABORATORY CERTIFICATION

[Prior to 4/10/96, see 567—Chapter 42]

PART A
GENERAL

567—83.1(455B) Authority, purpose, and applicability.

83.1(1) Authority. Pursuant to Iowa Code section 455B.113, a laboratory certification program is required for laboratories performing analyses of samples which are required to be submitted to the department as a result of Iowa Code provisions, rules, operation permits, or administrative orders. Pursuant to Iowa Code section 455B.114, the department may suspend or revoke the certification of a laboratory upon determination of the department that the laboratory no longer fulfills one or more of the requirements for certification.

83.1(2) Purpose. The purpose of these rules is to provide the procedures for laboratories to use to apply for certification, to establish laboratory certification fees, to maintain certification, and to provide the appropriate methods and references for evaluating laboratory competence including the requirements for laboratories to become certified.

83.1(3) Applicability to environmental program areas.

a. Water supply (drinking water). The requirements of this chapter apply to all laboratories conducting drinking water analyses pursuant to 567—Chapters 40, 41, 42, 43, and 47. Routine, on-site monitoring for alkalinity, calcium, conductivity, residual disinfectant, orthophosphate, pH, silica, temperature, turbidity and on-site operation and maintenance-related analytical monitoring are excluded from this requirement, and may be performed by a Grade I, II, III, or IV certified operator meeting the requirements of 567—Chapter 81, any person under the supervision of a Grade I, II, III, or IV certified operator meeting the requirements of 567—Chapter 81, or a laboratory certified by the department to perform water supply analyses under this chapter.

b. Underground storage tanks. The requirements of this chapter also apply to all laboratories conducting underground storage tank analyses for petroleum constituents pursuant to 567—Chapter 135. Routine on-site monitoring conducted by or for underground storage tank owners for leak detection or a nonregulatory purpose is excluded from this requirement.

c. Wastewater. The requirements of this chapter also apply to all laboratories conducting analyses of wastewater, groundwater or sewage sludge pursuant to 567—Chapters 63, 67, and 69. Routine on-site monitoring for pH, temperature, dissolved oxygen, total residual chlorine and other pollutants that must be analyzed immediately upon sample collection, settleable solids, physical measurements such as flow and cell depth, and operational monitoring tests specified in 567—subrule 63.3(4) are excluded from this requirement.

d. Solid waste and contaminated sites. The requirements of this chapter also apply to all laboratories conducting analyses of solid waste parameters pursuant to 567—Chapters 100 through 130, contaminated site parameters pursuant to 567—Chapters 133 and 137, and regulated substances other than petroleum parameters regulated under 567—Chapter 135. Any parameter that must be analyzed immediately upon sample collection is excluded from the requirements of this chapter. Any samples collected or testing conducted that is not part of the specific monitoring required by the department for regulatory purposes are also excluded from the requirements of this chapter.

567—83.2(455B) Definitions.

“*Certified*” means a laboratory demonstrates to the satisfaction of the department its ability to consistently produce valid data within the acceptance limits as specified within the department’s requirements for certification and meets the minimum requirements of this chapter and all applicable regulatory requirements. A laboratory may be certified for an analyte, an analytical series, or an environmental program area, except in the UST program area, where certification for individual analytes is not allowed.

“*Environmental program area*” means the water supply (drinking water) program, underground storage tank program, wastewater program, or solid waste and contaminated site program pursuant to 83.1(3).

“*Manual for the Certification of Laboratories Analyzing Environmental Samples for the Iowa Department of Natural Resources*” (2003) (Iowa Manual) is incorporated by reference in this chapter.

Chapter 1 of the Iowa Manual pertains to certification of laboratories analyzing samples of drinking water and incorporates by reference the Manual for the Certification of Laboratories Analyzing Drinking Water, 4th edition, March 1997, EPA document 815-B-97-001.

Chapter 2 of the Iowa Manual, 2003, pertains to laboratories analyzing samples for the underground storage tank program.

Chapter 3 of the Iowa Manual, 2003, pertains to laboratories analyzing samples for wastewater and sewage sludge disposal programs.

Chapter 4 of the Iowa Manual, 2003, pertains to laboratories analyzing samples for the solid waste and contaminated site programs.

“*Performance evaluation (PE) sample*” means a reference sample provided to a laboratory for the purpose of demonstrating that a laboratory can successfully analyze the sample within limits of performance specified by the department. The true value of the concentration of the reference material is unknown to the laboratory at the time of analysis. A PE sample may also be referred to as a proficiency testing sample or PT sample.

“*Provisional certification*” means a laboratory has deficiencies, which must be corrected within the specified time frames listed in 83.7(2)“d,” but demonstrates to the satisfaction of the department its ability to consistently produce valid data within the acceptance limits as specified within the department’s certification requirements.

“*Revoked certification*” means a laboratory no longer fulfills the requirements of this chapter, and certification is revoked by the director upon determination of the director that the laboratory no longer fulfills the requirements for certification (455B.114).

“*Suspended certification*” means a temporary suspension of certification for a laboratory, conditional upon meeting the time frames in 83.7(4)“d” for the correction of the deficiency.

“*Temporary certification*” means short-term transitional certification granted in certain circumstances when the department implements certification in a new environmental program area.

PART B
CERTIFICATION PROCESS

567—83.3(455B) Application for laboratory certification.

83.3(1) Application forms. Application for laboratory certification, other than for temporary certification, shall be made on forms provided by the department and shall be accompanied by the nonrefundable fee specified in 83.3(2). The application for renewal of certification shall be made at least 60 days prior to the certification expiration date. The department may require submission of additional information necessary to evaluate the application. All required documentation must be supplied to the department prior to the on-site visit. Failure to submit a complete application may result in denial of the renewal.

83.3(2) Fees and expenses.

a. A nonrefundable fee for the administration, completion of on-site laboratory surveys and assessments, and enforcement of laboratory certification requirements shall be paid with the certification application.

(1) The on-site visit will not be conducted and certification will not be issued until the fees and expenses are paid and all other certification requirements are met. The fee for certification will not be refunded if an on-site visit is not performed.

(2) Out-of-state laboratories will be responsible for paying the expenses of an on-site visit, in addition to the standard certification fee if required, and the department or its agent will bill the out-of-state laboratory directly for the expenses.

(3) When a laboratory’s certification is changed to “provisional” or “suspended” and the period for correcting deficiencies extends beyond the certification period, the laboratory must continue to pay the required fees in order to maintain its certification status.

(4) Additional fees. Additional fees will be assessed for the following, and the department or its agent will bill the laboratory directly.

1. The laboratory is responsible for paying for any additional on-site visits, at a fee of \$300 per visit. An example of this is when an additional on-site visit is required when a laboratory seeks certification for an entirely new set of parameters for which it had previously not been certified.

2. When an on-site visit is required to inspect for deficiencies that the laboratory has been required to correct, the fee is \$500 per visit.

b. Certification in multiple environmental program areas. Where a laboratory is certified for the same analyte in more than one environmental program area, the laboratory must meet all the applicable certification requirements in addition to the payment of the fees.

c. The applicable fees shall be based on the type of analytical service provided as follows:

ANALYTICAL GROUP	REGULATORY PROGRAM & PARAMETERS ¹	FEE
Asbestos	SDWA	\$400
Basic Drinking Water	SDWA (includes total and fecal coliform bacteria, <i>E. coli</i> , heterotrophic plate count, nitrate, nitrite, and fluoride)	\$800
Basic Wastewater	CWA (includes BOD5, cBOD5, total suspended solids, and ammonia)	\$400
Bacteria	CWA (includes total coliform, fecal coliform, and enterococci bacteria)	\$800
	SDWA (includes total coliform, fecal coliform, <i>E. coli</i> , and heterotrophic plate count)	\$800
	SDWA & CWA combined	\$1,300
Dioxin	SDWA	\$800
Effluent Toxicity Testing	CWA	\$800
Inorganics, including metals	CWA metals, inorganic compounds, and physical characteristics (\$400 per analyte up to a maximum of \$1,600)	\$400 to 1,600
	SDWA (includes metals, nitrate, nitrite, ammonia, cyanide, fluoride, bromate, bromide, chlorite, and total organic carbon)	\$1,600
	SW/CS	\$1,600
	CWA & SDWA combined	\$2,400
	CWA & SW/CS combined	\$2,400
	CWA, SDWA, and SW/CS combined	\$2,800

ANALYTICAL GROUP	REGULATORY PROGRAM & PARAMETERS ¹	FEE
Radionuclides	CWA	\$400
	SDWA (includes gross alpha, gross beta, photon emitters, radium, strontium, tritium, and uranium)	\$400
	SDWA & CWA combined	\$650
Synthetic Organic Chemicals (SOC)	CWA	\$1,600
	SDWA	\$1,600
	SW/CS	\$1,600
	CWA & SDWA combined	\$2,400
	CWA & SW/CS combined	\$2,400
	CWA, SDWA, and SW/CS combined	\$2,800
Volatile Organic Chemicals (VOC)	CWA	\$1,600
	SDWA	\$1,600
	SW/CS	\$1,600
	CWA & SDWA combined	\$2,400
	CWA & SW/CS combined	\$2,400
	CWA, SDWA, and SW/CS combined	\$2,800
Underground Storage Tank Program Methods (UST)	OA1 and OA2 for UST, CWA, & SW/CS programs	\$1,600
	OA1, OA2, PAH, and Air Gas for UST, CWA, & SW/CS programs	\$2,000
Other analyte ²	SDWA, CWA, UST, or SW/CS	\$400 per analyte

¹ CWA: Analysis of wastewater samples for the federal Clean Water Act.
SDWA: Analysis of drinking water samples for the federal Safe Drinking Water Act.
SW/CS: Analysis of water, soil, or solid samples for the solid waste or contaminated sites programs.
UST: Analysis of water and soil samples for the underground storage tank program.

² The fee for an additional analyte may be charged at the discretion of the appraisal authority.

d. Payment of fees. Fees shall be paid by bank draft, check, money order, or other means acceptable to the department, made payable to the Iowa Department of Natural Resources. Purchase orders are not an acceptable form of payment.

83.3(3) Reciprocity. Reciprocal certification of out-of-state laboratories by Iowa, and of Iowa laboratories by other states or accreditation providers, is encouraged. A laboratory must meet all Iowa certification criteria and pay all applicable fees as listed in this chapter. Any laboratory which is granted reciprocal certification in Iowa using primary certification from another state or provider is required to report any change in certification status from the accrediting state or provider to the department within 14 days of notification. A laboratory that loses primary certification, either in its resident state program or third-party accreditation program, will also immediately lose certification for the same program area and parameters in Iowa, pursuant to 83.7(5)“a”(9).

a. *Out-of-state laboratories.* Where an out-of-state laboratory has received an on-site visit within its own state, the fee for certification shall not be reduced if an on-site visit is not performed by Iowa.

b. *Third-party accreditation.* The department may accept third-party accreditation from national accreditation providers on an individual basis.

567—83.4(455B) Procedure for initial certification for laboratories analyzing solid waste and contaminated site program parameters.

83.4(1) *Implementation process.* All laboratories seeking certification to perform solid waste or contaminated site analyses shall provide a letter of intent requesting certification from the department. The letter shall include a statement that the laboratory is capable of performing the analyses for which certification is requested and that the laboratory intends to participate in blind PE testing using the approved methods.

a. Letter of intent. Laboratories submitting a letter of intent by April 1, 2004, will be issued a letter granting temporary certification. The temporary certification will be effective until the laboratory is certified through the on-site visit. Laboratories submitting applications after April 1, 2004, will not be issued temporary certification and must apply for certification as provided for in 83.5(455B). Temporary certification will be denied if a laboratory fails to submit a completed application with the appropriate fee for full certification within the time frame established by the department.

b. Application. The department or its designee will schedule an on-site visit for each laboratory with temporary certification unless the on-site visit is waived by the department as provided by the reciprocity agreements pursuant to 83.4(1)“d.” The department will request a completed application from the laboratory at least 60 days prior to the on-site visit. The completed application and the correct fee must be received by the department no later than 30 days before the on-site visit. Temporary certification will be denied and the on-site visit will not take place if the application is not complete and the fee is not timely received.

c. Performance evaluation (PE) testing. Participation in PE testing using the approved method(s) for which certification is requested must be initiated within 30 days after the laboratory submits the letter of intent. PEs consist of analyzing product-spiked samples in a particular matrix provided by the testing organization to determine if a laboratory’s analytical results are within the acceptance range. Acceptable results on the PE are required in order for the laboratory to receive final certification. Temporary certification will be denied if the laboratory fails to initiate the PE. An independent performance testing organization meeting the requirements of Chapter 4 in the “Manual for the Certification of Laboratories Analyzing Environmental Samples for the Iowa Department of Natural Resources” (2003) must be used.

d. On-site visits. Upon application to the department by a laboratory with temporary certification, the director or designee will contact the laboratory and a date will be established for an on-site visit. The criteria given in the “Manual for the Certification of Laboratories Analyzing Environmental Samples for the Iowa Department of Natural Resources” (2003), specifically Chapter 4 regarding solid waste, will be used during the on-site visit to evaluate qualifications of laboratory equipment, procedures, records, and personnel. The on-site visit requirement may be waived for out-of-state laboratories desiring certification where EPA or the resident state has a certification program equivalent to Iowa’s, an on-site visit has been conducted within the past two years, and a copy of the on-site visit report is provided to the department.

83.4(2) *Letter of certification.* If the physical facilities and equipment of the laboratory meet the criteria set forth in the “Manual for the Certification of Laboratories Analyzing Environmental Samples for the Iowa Department of Natural Resources” (2003), and the laboratory personnel have properly demonstrated proficiency with the procedures specified in the manual, the laboratory will be issued a letter granting certification. The letter of certification will state the essential personnel, the specific parameters and analytical methods for which the laboratory is certified and may contain conditions deemed necessary by the department to ensure that the laboratory meets all requirements of this chapter.

567—83.5(455B) Procedures for certification of new laboratories or changes in certification.

Laboratories that wish to become certified to conduct testing for an analyte or a method after the deadline for initial certification has passed, and any laboratory seeking initial certification, shall follow the procedures specified in 567—83.6(455B) for laboratory recertification. For changes in certification, the relevant fee must accompany the application where appropriate.

567—83.6(455B) Laboratory recertification. Laboratories shall be recertified every two years after initial certification. Applications for recertification must be on forms provided by the department and must be postmarked at least 60 days prior to the renewal date. Applications shall be accompanied by the fee specified in 83.3(2). To be recertified, laboratories must meet the following requirements.

83.6(1) Laboratories must use the approved methodology for all analyses the results of which are to be submitted to the department. A laboratory may not analyze and report data from samples collected for an environmental program area until certified in that area.

83.6(2) Certified laboratories must satisfactorily analyze PEs at least once every 12 months for each analyte by each method for which the laboratory wishes to retain certification unless a PE sample is not available for the particular analyte or method. Results must be submitted to Iowa department of natural resources or as otherwise directed, along with a statement of the method used within 30 days of receipt from the provider. The laboratory must maintain records of all PE samples for a minimum of 5 years.

83.6(3) Laboratories must notify the department, in writing, within 15 days of major changes in essential personnel, equipment, laboratory location, or other major change which might alter or impair analytical capability. An example of a major change in essential personnel includes the loss or replacement of the laboratory supervisor, or a trained and experienced analyst is no longer available to analyze a particular parameter for which certification has been granted.

83.6(4) Site visits.

a. Certification of the University of Iowa Hygienic Laboratory. The department has designated the University of Iowa Hygienic Laboratory (UHL) as its appraisal authority for laboratory certification. The U.S. Environmental Protection Agency is responsible for the certification of UHL for the SDWA program, and the UHL quality assurance officer is responsible for the certification of UHL for those programs with no available EPA certification program, including wastewater, underground storage tank, solid waste, and contaminated site programs. The UHL quality assurance officer reports directly to the office of the UHL director and operates independently of all areas of the laboratory generating data to ensure complete objectivity in the evaluation of laboratory operations. The quality assurance officer will schedule a biennial on-site inspection of the UHL and review results for acceptable performance. Inadequacies or unacceptable performance shall be reported by the quality assurance officer to the UHL and the department for correction. The department shall be notified if corrective action is not taken.

b. On-site visits. Laboratories must consent to a periodic site visit by the department or its designee, at least every two years. However, an on-site visit may be conducted more frequently if the laboratory undergoes a major change which may alter or impair analytical capability, fails a PE sample analysis, or if the department questions an aspect of data submitted which is not satisfactorily resolved.

83.6(5) Period of validity. Certification shall be valid for a period not to exceed two years from the date of issuance, except in the case of reciprocal certification of an out-of-state laboratory. Reciprocal certification shall be valid for a period equal to that of the resident state in which the laboratory is certified, but shall not exceed two years. Certification shall remain in effect provided a laboratory has submitted a timely and complete application, until certification is either renewed or revoked.

83.6(6) Reporting requirements. Laboratories may not analyze or report sample results for any analyte, analytical series, or environmental program area until the initial certification status of “certified” or “temporary” has been granted by the department. Any data generated before certification status is granted will be considered invalid for compliance purposes. A laboratory with “provisional” status may analyze and report analyses for compliance purposes.

A certified laboratory may contract analyses to another certified laboratory. The responsibility lies with the primary certified laboratory contracting for services to verify that the secondary contracting laboratory is certified by the department and to ensure that reporting requirements and deadlines are met.

a. Water supply program.

(1) Certified laboratories must report to the department, or its designee such as UHL, all analytical test results for all public water supplies, using forms provided or approved by the department or by electronic means acceptable to the department. If a public water supply is required by the department to collect and analyze a sample for an analyte not normally required by 567—Chapters 41 and 43, the laboratory testing for that analyte must also be certified and report the results of that analyte to the department. It is the responsibility of the laboratory to correctly assign and track the sample identification number as well as facility ID and source/entry point data for all reported samples.

1. The following are examples of sample types for which data results must be reported:

- Routine: a regular sample which includes samples collected for compliance purposes from such locations as the source/entry point and in the distribution system, at various sampling frequencies;
- Repeat: a sample which must be collected after a positive result from a routine or previous repeat total coliform sample, per 567—41.2(455B). Repeat samples must be analyzed at the same laboratory from which the associated original routine sample was analyzed;
- Confirmation: a sample which verifies a routine sample, normally used in determination of compliance with a health-based standard, such as nitrate;
- Special: a nonroutine sample, such as raw, plant, and troubleshooting samples, which cannot be used to comply with monitoring requirements assigned by the department;
- Maximum residence time: a sample which is collected at the maximum residence time location in the distribution system, usually for disinfection byproduct measurement; and
- Replacement: a sample which replaces a missed sample from a prior monitoring period resulting in a monitoring violation.

2. The following additional types of data must be reported to the department:

- Monthly Operation Report (MOR) data which has been specifically required by the department to demonstrate compliance with public health standards;
- Chemical results not required to be analyzed but which are detected during analysis, such as detection of a synthetic organic chemical during a routine analysis of that related analytical series for compliance reporting; and
- Raw water sampling results specifically covered by 567—Chapters 40 to 43 for new surface water or groundwater sources, or reconstruction of groundwater sources.

3. The following are examples of data results that are not required to be reported by the laboratory to the department:

- Routine MOR data;
- Distribution samples for the Total Coliform Rule for water main repair or installation; or
- Results for contaminants that are not required by the department to be analyzed, which are below detection level.

4. The sample type cannot be changed after submittal to the laboratory, without written approval by the department. The prescreening, splitting, or selective reporting of compliance samples is not allowed.

(2) Certified laboratories must report all analytical results to the public water supply for which the analyses were performed.

(3) Analytical results must be reported to and received by the department's designee by the seventh day of the month following the month in which the samples were analyzed.

(4) In addition to the monthly reporting of the analytical results, the following results must be reported within 24 hours of the completion of the analysis to the department by facsimile transmission (fax) or other method acceptable to the department, and to the public water supply for which the analyses were conducted:

1. Results of positive routine coliform bacteria samples, and all repeat and follow-up samples, reported within 24 hours of the completion of each sample's analysis.

2. Results of any contaminant which exceeds public drinking water standards (maximum contaminant level, treatment technique, or health advisory), and any subsequent confirmation samples, excluding lead and copper.

(5) If requested by the department, certified laboratories shall report their method detection levels, levels of quantitation, and any other pertinent information when reporting results for public water supplies.

b. Underground storage tank program. Certified laboratories must report to the client requesting the analysis and include the information required in 567—subrule 135.10(2) in their laboratory report.

c. Wastewater program. Certified laboratories must report to the client requesting the analysis and include the information required in 567—paragraphs 63.2(2) “b” to “e” in their laboratory report.

d. Solid waste and contaminated site programs. Certified laboratories must report to the client requesting the analysis and include the information required in 567—paragraph 83.6(7) “d” and 567—subrule 103.2(8).

83.6(7) Performance evaluation (PE) and acceptance limits. All PE samples must be obtained from EPA; a provider accredited by EPA, the National Environmental Laboratory Accreditation Program (NELAP) or National Institute of Standards and Technology (NIST); or other provider acceptable to the department. All PE samples must have statistical acceptance limits. Certain environmental program areas may have specific PE requirements, as follows:

a. Water supply program. Laboratories must be able to achieve at least the method detection limit for each specific analyte as listed in 567—Chapter 41, in addition to any method detection limit requirement listed in this paragraph.

(1) Volatile organic chemical (VOC). Analysis for VOCs shall only be conducted by laboratories certified by EPA or the department or its authorized designee according to the following conditions. To receive approval to conduct analyses for the VOC contaminants in 567—subparagraph 41.5(1) “b”(1), except for vinyl chloride, the laboratory must:

1. Analyze PE samples provided by EPA, the department, or a third-party provider acceptable to the department, at least once a year by each method for which the laboratory desires certification.

2. Achieve the quantitative acceptance limits for at least 80 percent of the regulated organic chemicals included in the PE sample, except for vinyl chloride.

3. Achieve quantitative results on the PE samples within plus or minus 20 percent of the actual amount of the substances when the actual amount is greater than or equal to 0.010 mg/L.

4. Achieve quantitative results on the PE samples within plus or minus 40 percent of the actual amount of the substances when the actual amount is less than 0.010 mg/L.

5. Achieve a VOC method detection limit of 0.0005 mg/L.

(2) Vinyl chloride. To receive approval for vinyl chloride, the laboratory must:

- 1. Analyze PE samples which include vinyl chloride provided by EPA, the department, or a third-party provider acceptable to the department, at least once a year by each method for which the laboratory desires certification.
 - 2. Achieve quantitative results on the PE samples within plus or minus 40 percent of the actual amount of vinyl chloride.
 - 3. Achieve a method detection limit of 0.0005 mg/L.
- (3) Synthetic organic chemical (SOC). Analysis for SOC's shall be conducted only by laboratories certified by EPA or the department or its authorized designee. To receive approval to conduct analyses for the SOC contaminants in 567—subparagraph 41.5(1)“b”(2), the laboratory must:
- 1. Analyze PE samples which include those substances provided by EPA, the department, or a third-party provider acceptable to the department, at least once a year by each method for which the laboratory desires certification.
 - 2. For each contaminant that has been included in the PE sample, achieve quantitative results on the analyses that are within the following acceptance limits:

ACCEPTANCE LIMITS

<u>Contaminant</u>	<u>Acceptance Limit, in percent</u>
Alachlor	(+ or -) 45
Aldicarb	2 standard deviations
Aldicarb sulfoxide	2 standard deviations
Aldicarb sulfone	2 standard deviations
Atrazine	(+ or -) 45
Benzo(a)pyrene	2 standard deviations
Carbofuran	(+ or -) 45
Chlordane	(+ or -) 45
2,4-D	(+ or -) 50
Dalapon	2 standard deviations
Dibromochloropropane (DBCP)	(+ or -) 40
Di(2-ethylhexyl)adipate	2 standard deviations
Di(2-ethylhexyl)phthalate	2 standard deviations
Dinoseb	2 standard deviations
Diquat	2 standard deviations
Endothall	2 standard deviations
Endrin	(+ or -) 30
Ethylene dibromide (EDB)	(+ or -) 40
Glyphosate	2 standard deviations
Heptachlor	(+ or -) 45

Heptachlor epoxide	(+ or -) 45
Hexachlorobenzene	2 standard deviations
Hexachlorocyclopentadiene	2 standard deviations
Lindane	(+ or -) 45
Methoxychlor	(+ or -) 45
Oxamyl	2 standard deviations
Pentachlorophenol	(+ or -) 50
Picloram	2 standard deviations
Polychlorinated biphenyls (PCBs as decachlorobiphenyl)	0 - 200
Simazine	2 standard deviations
2,3,7,8-TCDD (Dioxin)	2 standard deviations
2,4,5-TP (Silvex)	2 standard deviations
Toxaphene	(+ or -) 45

(4) Inorganic chemical (IOC). Analysis for IOCs shall be conducted only by laboratories certified by EPA or the department or its authorized designee. To receive approval to conduct analyses for ammonia, antimony, arsenic, asbestos, barium, beryllium, cadmium, chromium, cyanide, fluoride, mercury, nitrate, nitrite, selenium and thallium, the laboratory must:

1. Analyze PE samples provided by EPA, the department, or a third-party provider acceptable to the department, at least once a year.
2. For each contaminant that has been included in the PE sample and for each method for which the laboratory desires certification, achieve quantitative results on the analyses that are within the following acceptance limits:

ACCEPTANCE LIMITS

<u>Contaminant</u>	<u>Acceptance Limit</u>
Ammonia	(+ or -) 20% at greater than or equal to 0.3 mg/L
Antimony	(+ or -) 30% at greater than or equal to 0.006 mg/L
Arsenic	(+ or -) 30% at greater than or equal to 0.003 mg/L
Asbestos	2 standard deviations based on study statistics
Barium	(+ or -) 15% at greater than or equal to 0.15 mg/L
Beryllium	(+ or -) 15% at greater than or equal to 0.001 mg/L
Cadmium	(+ or -) 20% at greater than or equal to 0.002 mg/L
Chromium	(+ or -) 15% at greater than or equal to 0.01 mg/L
Cyanide	(+ or -) 25% at greater than or equal to 0.1 mg/L
Fluoride	(+ or -) 10% at greater than or equal to 1 to 10 mg/L
Mercury	(+ or -) 30% at greater than or equal to 0.0005 mg/L
Nitrate	(+ or -) 10% at greater than or equal to 0.4 mg/L
Nitrite	(+ or -) 15% at greater than or equal to 0.4 mg/L
Selenium	(+ or -) 20% at greater than or equal to 0.01 mg/L
Thallium	(+ or -) 30% at greater than or equal to 0.002 mg/L

(5) Lead and copper. To obtain certification to conduct analyses for lead and copper, laboratories must:

1. Analyze PE samples that include lead and copper provided by EPA, the department, or a third-party provider acceptable to the department, at least once a year by each method for which the laboratory desires certification; and

2. Achieve quantitative results on the analyses that are within the following acceptance limits:

- Lead: plus or minus 30 percent of the actual amount in the PE sample when the actual amount is greater than or equal to 0.005 mg/L. The practical quantitation level or PQL for lead is 0.005 mg/L; and
- Copper: plus or minus 10 percent of the actual amount in the PE sample when the actual amount is greater than or equal to 0.050 mg/L. The practical quantitation level or PQL for copper is 0.050 mg/L; and

3. Be currently certified by EPA or the department to perform analyses to the specifications described in 567—paragraph 41.4(1)“g.”

(6) Disinfection byproducts. To obtain certification to conduct analyses for disinfection byproducts listed in 567—paragraph 41.6(1)“b,” laboratories must:

1. Analyze PE samples approved by EPA, the department, or a third-party provider acceptable to the department at least once a year by each method for which the laboratory desires certification;

2. Achieve quantitative results within the acceptance limit on a minimum of 80 percent of the analytes included in each PE sample. The acceptance limit is defined as the 95 percent confidence interval calculated around the mean of the PE study data. However, the acceptance limit range shall not exceed plus or minus 50 percent or be less than plus or minus 15 percent of the study mean; and

3. Be currently certified by EPA or the department to perform analyses to the specifications described in 567—paragraph 41.6(1)“d.”

- b. Underground storage tank program.* A laboratory must achieve acceptable results on PE samples every 12 months within plus or minus 20 percent of the true value for individual compounds (i.e., benzene, ethylbenzene, toluene, xylene by OA-1) and plus or minus 40 percent of the true value for multicomponent materials (i.e., gasoline, diesel fuel, motor oil by either OA-1 or OA-2). The PE samples must be provided by EPA, the department, or a third-party provider acceptable to the department.

- c. Wastewater program.* Achieve acceptable quantitative results every 12 months on PE samples equivalent to those used in the Water Pollution (WP) proficiency program, or the Discharge Monitoring Report Quality Assurance (DMRQA) program, both of which are administered by EPA or its designee.

- d. Solid waste and contaminated site programs.* Achieve acceptable quantitative results every 12 months on PE samples provided by EPA, the department, or a third-party provider acceptable to the department.

567—83.7(455B) Criteria and procedure for provisional, suspended, and revoked laboratory certification.

83.7(1) Provisional certification criteria.

- a.* The department may downgrade certification to “provisional” status based on cause. The reasons for which a laboratory may be downgraded to “provisionally certified” status include, but are not limited to, the following list.

- (1) Failure to analyze a performance evaluation (PE) sample annually within Iowa acceptance limits;

- (2) Failure to notify the department within 15 days of changes in essential personnel, equipment, laboratory facilities or other major change which might impair analytical capability;

(3) Failure to satisfy the department that the laboratory is maintaining the required standard of quality based on an on-site visit;

(4) Failure to report compliance data in a timely manner to the department or the client, thereby preventing timely compliance with environmental program regulations.

b. The department may assess an administrative penalty for a laboratory's failure to comply with the laboratory certification or reporting requirements.

c. A laboratory will not be granted provisional certification by the department for contaminants which pose an acute risk to human health, including nitrate, nitrite, fecal coliform bacteria, and *Escherichia coli* bacteria.

83.7(2) Provisional certification procedure.

a. *Notification to the laboratory.* If a laboratory is subject to downgrading to "provisional" status on the basis of 83.7(1), the department will notify the laboratory or owner in writing of the downgraded status. Certification may be downgraded to provisional for an analyte, a related analytical series, an environmental program area, or the entire laboratory.

b. *Reporting.* A provisionally certified laboratory may continue to analyze samples for compliance purposes, but must notify the laboratory's IDNR-regulated clientele and other state certifying agencies of the change in laboratory certification status. If there is cause to question the quality of the data generated by the laboratory, the department may suspend the laboratory's ability to submit data to the department for any or all analytes, pursuant to 83.7(3), which includes suspension of the ability of the laboratory's client to report the data of questionable quality to the department.

c. *Right to appeal.* There is no appeal for this process, as it does not affect a laboratory's ability to analyze and report to the department.

d. *Correction of deficiencies.*

(1) If a laboratory failed to analyze a PE sample within acceptance limits, the laboratory has 60 days from receipt of the notification of the failure to identify and correct the problem to the department's satisfaction, and analyze a second PE sample. If the laboratory fails to analyze this second sample within acceptance limits and has had acceptable PE sample results within the last year, the department will downgrade the laboratory to "provisionally certified" status and notify the laboratory in writing.

(2) Once the department notifies a laboratory in writing that it has been downgraded to "provisionally certified" status, the laboratory must correct the problem within the following time frames, unless a written extension is obtained from the department. If the problem is not corrected, the laboratory is subject to suspension or revocation for that analyte, related analytical series, environmental program area, or the entire laboratory.

1. Unacceptable PE sample result within two months of notification.

2. Procedural deficiency within three months of notification.

3. Administrative deficiency within three months of notification.

4. Minor equipment deficiency within three months of notification. Examples of a minor equipment deficiency are inadequate analytical balances or incubators.

(3) The laboratory shall review the problems cited and, within the time period designated by the department, specify in writing to the department the corrective actions being taken, including an appropriate implementation schedule. The department shall consider the adequacy of the response and notify the laboratory of its certification status in a timely basis by mail, and may follow up to ensure corrective actions have been taken.

e. *Reinstatement.* Certification will be reinstated when the laboratory can demonstrate that all conditions for laboratory certification have been met to the satisfaction of the department and that the deficiencies which resulted in provisional certification status have been corrected. This may include an on-site visit, successful analysis of PE samples, or any other measure that the department deems appropriate.

83.7(3) Suspended certification criteria.

a. The department may downgrade certification to “suspended” status based on cause. The reasons for which a laboratory may be downgraded to “suspended” status include, but are not limited to, the following list.

(1) Failure to analyze a PE sample annually for contaminants which pose an acute risk to human health, including nitrate, nitrite, fecal coliform bacteria, and *Escherichia coli* bacteria, or which pose an imminent risk to the environment;

(2) Failure to analyze a PE sample annually within Iowa acceptance limits for contaminants which pose an acute risk to human health, including nitrate, nitrite, fecal coliform bacteria, and *Escherichia coli* bacteria, or which pose an imminent risk to the environment;

(3) Failure to correct previously identified deficiencies, which resulted in “provisional” certification status, within the prescribed time frames of 83.7(2) “d”;

(4) Failure to analyze a PE sample within Iowa acceptance limits when there is not a reliable history of successful PE sample analysis within the past 12 months;

(5) Failure to satisfy the department that the laboratory is producing accurate data.

b. Administrative penalty. The department may assess an administrative penalty for a laboratory’s failure to comply with the laboratory certification or reporting requirements.

c. Emergency certification suspension. The department may suspend certification without providing notice and opportunity to the laboratory to be heard if the department finds that the public health, safety, or welfare imperatively requires emergency action, and incorporates a finding to that effect in its administrative order, pursuant to 561—subrule 7.16(6).

83.7(4) Suspended certification procedure.

a. *Notification to the laboratory.* If a laboratory is subject to downgrading to “suspended” status on the basis of 83.7(3), the department will notify the laboratory or owner in writing of its intent to suspend certification in accordance with 561—7.16(17A,455A). Certification may be suspended for an analyte, a related analytical series, an environmental program area, or the entire laboratory.

b. *Reporting.* Once the suspension is effective, a laboratory must immediately discontinue analysis and reporting of compliance samples, may not analyze or report samples for compliance with departmental standards, and must notify the laboratory’s Iowa regulated clientele and other state certifying agencies of the change of the laboratory certification status. Any results generated during the period of suspension may not be used for compliance purposes by the department.

c. *Right to appeal.*

(1) The laboratory may appeal this decision by filing a written notice of appeal and request an administrative hearing with the department director within 30 days of receipt of the notice of suspension of certification. Contested case procedures under 561—Chapter 7 shall govern administration of the appeal.

The appeal must identify the specific portion(s) of the department action being appealed and be supported with a statement of the reason(s) for the challenge and must be signed by a responsible official from the laboratory such as the president or owner for a commercial laboratory, or the laboratory supervisor in the case of a municipal laboratory, or the laboratory director for a state laboratory.

(2) If no timely notice of appeal is filed, suspension is effective 30 days after receipt of the notice of suspension unless an emergency suspension order is in effect.

d. *Correction of deficiencies.*

(1) If a laboratory failed to analyze a PE sample within acceptance limits, the laboratory has 30 days from receipt of the notification of the failure to identify and correct the problem to the department’s satisfaction. If the laboratory fails to analyze this second sample within acceptance limits, the department will downgrade the laboratory to “suspended” status and notify the laboratory in writing.

(2) Once the department notifies a laboratory in writing that it has been downgraded to suspended status, the laboratory must correct the problem within the following timetable, unless a written extension is obtained from the department. If the problem is not corrected, the laboratory is subject to revocation for that analyte, related analytical series, environmental program area, or the entire laboratory.

1. Unacceptable PE sample result within two months of notification.
2. Procedural deficiency within three months of notification.
3. Administrative deficiency within three months of notification.
4. Minor equipment deficiency within three months of notification. Examples of a minor equipment deficiency are inadequate analytical balances or incubators.
5. Major equipment deficiency within six months of notification. An example of a major equipment deficiency would be the inability of existing complex analytical equipment to produce acceptable results, such as a chromatograph or spectrophotometer.

(3) The laboratory shall review the problems cited and, within the time period designated by the department, specify in writing to the department the corrective actions being taken including an appropriate implementation schedule. The department shall consider the adequacy of the response and notify the laboratory of its certification status in a timely basis by mail, and may follow up to ensure that corrective actions have been taken.

e. Reinstatement.

(1) Fee.

1. The laboratory will not be required to pay an additional fee if recertification affects an analyte or related analytical series, provided that:

- The laboratory is currently certified for other analytes, or
- A fee was paid within the two-year certification period for that related analytical series and the laboratory is certified for other parameters within that related analytical series.

2. A fee will be required if suspension affects a related analytical series effectively deleting that fee group from certification (such as all microbiological parameters in SDWA-MICRO), an environmental program area, or the entire laboratory. A fee will also be required if an additional on-site visit is required.

(2) Certification will be reinstated when the laboratory can demonstrate that all conditions for laboratory certification have been met to the department's satisfaction and, in particular, that the deficiencies which produced the suspension have been corrected. This may include an on-site visit, successful analysis of unknown samples, or any other measure that the department deems appropriate.

83.7(5) *Revoked certification criteria.*

a. The department may revoke certification for cause. The reasons for which a laboratory's certification may be revoked include, but are not limited to, the following:

- (1) For laboratories of any status, failure to analyze a PE sample within Iowa acceptance limits;
- (2) Failure to satisfy the department that the laboratory has corrected deficiencies identified during the on-site visit within three months for a procedural or administrative deficiency or within six months for an equipment deficiency;
- (3) Submission of a PE sample to another laboratory for analysis and reporting the data as its own;
- (4) Falsification of data or other deceptive practices;
- (5) Failure to use required analytical methodology for analyses submitted to the department;
- (6) Failure to satisfy the department that the laboratory is maintaining the required standard of quality based on the on-site visit;
- (7) Persistent failure to report compliance data to the regulated client or the department in a timely manner, thereby preventing compliance with state regulations and endangering public health;

(8) Subverting compliance with state regulations by actions such as changing the sample type for a noncompliance sample to a compliance sample after its submission to the laboratory, allowing compliance samples to be changed to other noncompliance sample types, or selective reporting of split sample results; or

(9) For laboratories certified through a reciprocal agreement with another state or third-party accreditation program, loss of certification in either the resident state or third-party accreditation program is cause for immediate revocation of certification in Iowa for the same parameters or program areas for which certification was lost.

b. The department may either downgrade or revoke certification based on cause.

c. Emergency revocation. The department may revoke certification without providing notice and opportunity to the laboratory to be heard if the department finds that the public health, safety, or welfare imperatively requires emergency action, and incorporates a finding to that effect in its administrative order, pursuant to 561—subrule 7.16(6).

d. Laboratory-requested revocation. The department may revoke certification upon receipt of a written request by the certified laboratory for removal from the certification program.

83.7(6) *Revoked certification procedure.*

a. *Notification to the laboratory.* Except for the instance when the laboratory voluntarily requests revocation in 83.7(5) “*d*,” if a laboratory is subject to revocation on the basis of 83.7(5), the department will notify the party in writing of its intent to revoke certification in accordance with 561—7.16(17A,455A). Certification may be revoked for an analyte, a related analytical series, an environmental program area, or the entire laboratory.

b. *Reporting.* Once revocation is effective, a laboratory must immediately discontinue analysis and reporting of compliance samples, shall not analyze or report samples for compliance with departmental standards, and must notify the laboratory’s Iowa-regulated clientele and other state certifying agencies of the change of the laboratory certification status within three business days of receipt of the final notice. Any results generated after revocation may not be used for compliance purposes by the department.

c. *Right to appeal.* There is no appeal process for revocation of an analyte or a related analytical series unless the analyte(s) represents an entire environmental program area, such as underground storage tank parameters, or the entire laboratory. When the laboratory requests revocation pursuant to 83.7(5) “*d*,” the revocation will be issued promptly and will be effective immediately with no appeal process.

(1) For an environmental program area or for the entire laboratory, the laboratory may appeal this decision by filing a written notice of appeal and request for an administrative hearing with the department director within 30 days of receipt of the notice of revocation of certification. Contested case procedures under 561—Chapter 7 shall govern further administration of the appeal.

The appeal must identify the specific portion(s) of the department action being appealed and be supported with a statement of the reason(s) for the challenge and must be signed by a responsible official from the laboratory such as the president or owner for a commercial laboratory, or the laboratory supervisor in the case of a municipal laboratory, or the laboratory director for a state laboratory.

(2) If no timely notice of appeal is filed within the 30-day time period, revocation is effective 30 days after receipt of the notice of intent.

d. *Reinstatement.* A laboratory which has had its certification revoked may apply for certification in accordance with 83.3(455B) once the deficiencies have been corrected.

These rules are intended to implement Iowa Code sections 455B.113 through 455B.115.

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CHAPTERS 84 to 89
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